K122768

JAN 18 2013

510(k) SUMMARY

Dornier MedTech America, Inc.'s GENESIS

Submitter Name and Address:	Dornier MedTech America, Inc. 1155 Roberts Blvd. Kennesaw, GA 30144
Contact Person:	John Hoffer Vice President, Quality/Regulatory/Clinical
Phone Number:	770-514-6163
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Date Prepared:	December 18, 2012
Device Trade Name(s):	GENESIS
Device Common Name / Classification Name:	Image-intensified fluoroscopic x-ray system (Product Code: JAA)
Predicate Device(s):	Dornier Urotract (K955019) Siemens Uroskop Omnia (K101491)
General Device Description:	The Dornier GENESIS is an Image Intensified Fluoroscopic X-ray System (i.e., a solid state x-ray imager (flat panel/digital imager)). The GENESIS consists of the following components: an x-ray generator and tube housing, flat panel detector, monitors and procedure table. An X-ray cabinet contains system elements such as the X-ray generator, power electronics and electronics for the imaging chain.
Intended Use / Indications for Use:	The Dornier Genesis is an image intensified, fluoroscopic x-ray system that is intended for use in a wide field of applications, including all general examinations in urology and gynecology, as well as endoscopic and contrast examinations, imaging with radiography and/or fluoroscopy on patients in either the horizontal or vertical position.
Technological Characteristics:	From a clinical perspective and comparing design specifications, the Dornier GENESIS and the predicate devices are substantially equivalent. Based on the technological characteristics and overall performance of the devices, Dornier believes that no significant differences exist between the proposed product and the predicate devices.

Performance Data

The GENISIS was tested per the following recognized testing standards:

- IEC 60601-1: Medical electrical equipment. Part 1: General requirements for safety (2005).
- IEC 60601-1-2: Medical electrical equipment. Part 1-2: General requirements for safety; Electromagnetic compatibility-requirements and tests (2007).
- IEC 60601-1-3: Medical electrical equipment. Part 1: General requirements for safety; general requirements for radiation protection in diagnostic X-ray equipment (2008).
- IEC 60601-1-6: Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability (2008).
- IEC 60601-2-7: Medical electrical equipment. Part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators (1998).
- IEC 60601-2-28: Medical electrical equipment. Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis (2010).
- IEC 60601-2-54: Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (2009).

In addition, per FDA's Guidance Document entitled *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices* (August 6, 1999), the company completed all required nonclinical and clinical testing for the subject device. In all instances, the GENESIS functioned as intended and the results observed were as expected. With regard to the completed concurrence study, the results confirm that the GENESIS has at least equivalent performance to the predicate Urotract.

Substantial Equivalence

Based on the technological characteristics and overall performance of the devices, Dornier believes that the GENESIS and the predicate devices selected are substantially equivalent and that the differences between the devices are minor and do not raise new issues of safety or effectiveness.

In sum, the GENESIS is as safe and effective as the identified predicate devices. The GENESIS has the same intended uses/indications for use and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the GENESIS and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the GENESIS is as safe and effective as the identified predicate devices. Thus, the GENESIS is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 18, 2013

Dornier MedTech America, Inc.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K122768
Trade/Device Name: GENESIS
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: January 2, 2013
Received: January 2, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122768

Device Name: Dornier GENESIS

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Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Sean M. Boyd -S

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K122768